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(54) HELICAL BALLOON PERFUSION ANGIOPLASTY CATHETER

PERFUSIONSKATHETER MIT SCHRAUBENFÖRMIGEM BALLON FÜR DIE ANGIOPLASTIE

CATHETER A BALLON HELICOIDAL DE PERFUSION POUR ANGIOPLASTIE

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Description

FIELD OF THE INVENTION

The invention relates to balloon catheters of the type used in balloon angioplasty and similar medical procedures.

BACKGROUND OF THE INVENTION

Over the last several years great advances have been made in the feasibility and success of balloon angioplasty, both in peripheral arteries and coronary arteries. Percutaneous translumina coronary angioplasty (PTCA) has now become an established technique for treatment of atherosclerotic obstructions in coronary arteries. For many patients, this procedure eliminates the need to undergo coronary bypass surgery.

Recent studies have suggested that the effectiveness of balloon angioplasty (including PTCA) increases if the inflation of the balloon can be more gradual and if the duration of balloon inflation can be lengthened. Since conventional balloons entirely occlude the artery when inflated (including any side branches in the artery adjacent the balloon), the duration of balloon inflation often is limited by patient tolerance of chest pain and hemodynamic or electrical instability, as well as eventual tissue necrosis distally of the balloon if the circulation is cut off too long.

A variety of techniques have been proposed to mitigate these limitations, including various drug treatments (e.g. pretreatment with lidocaine, nitroglycerin, etc.), retroperfusion via the coronary sinus, and even the use of general anesthesia. One tehcnique that mitigates many of these limitations is the use of a perfusion balloon catheter, such as that developed by Stack (see, e.g., D. Kereiakes & R. Stack, "Perfusion Angioplasty," Textbook of Interventional Cardiology (E. Topol, ed., 1990)). In these types of balloon catheters, the catheter shaft incudes side holes both proximally and distally of the balloon. These holes allow blood to enter the catheter lumen proximally of the balloon and then pass through the lumen into the artery distally of the balloon, thus preserving some blood flow even when the balloon is inflated. The shaft of such perfusion balloon catheters, however, is necessarily relatively large (in order to permit a significant amount of blood flow therethrough), and the catheter consequently is less flexible, limiting its use and effectiveness. Moreover, side branches of the artery may still be occluded by the balloon if the stenotic segment is near or spans such a branch. US-A-4 183 102 especially figure 5 discloses a prosthesis for alleviating a defect in a vessel wall. The toroidal sleeves are connected by small orifices in the walls of the sleeves

SUMMARY OF THE INVENTION

The invention provides a perfusion balloon catheter that avoids many of the drawbacks of the Stack-type balloon catheter. The balloon catheter of the invention comprises a thin walled collapsable and inflatable tube that has a proximal, generally straight portion, and a distal, helically coiled portion that is generally cylindrically shaped and defines an open lumen therethrough. Means is provided for securing the turns of the coil with respect to one another, such as by providing an outer or inner skin to which the turns adhere.

In use, the furled balloon catheter is inserted to the desired location and then inflated. Because the helically coiled portion defines a relatively large open lumen, blood flow through the balloon can continue even as the inflated balloon remains in place. This allows an extended period of inflation without the side effects attendant with conventional balloons (such as chest pain, etc.). Moreover, the diameter of the central lumen can allow for blood flow equivalent to or greater than the Stack-type balloon, without the size and rigidity problems experienced by those balloons.

Although the turns of the coiled balloon preferably abut one another, in certain embodiments one or more spaces in the helical coil wall can be provided (by spacing successive turns from one another) to facilitate blood flow through arterial side branches that otherwise would be occluded by conventional balloons (including Stack-type balloons). The helical balloon can also be easily configured to have a predetermined bend (or flexibility to bend) for procedures at or very near sharp arterial bends, such as by pre-configuring the balloon with a bend or by providing spaces in the helical coil to give it greater flexibility at certain points.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a helical balloon catheter of the invention;

Figure 2 shows the balloon catheter of Figure 1 advanced into an artherosclerotic artery and partially inflated;

Figure 3 shows the balloon catheter of Figure 2 fully inflated with a perfusion or contrast injection catheter advanced over the guide wire;

Figure 4 shows the balloon catheter of the invention in its furled configuration being advanced into an artherosclerotic artery, with a pushing catheter advanced over the guide wire;

Figure 5 shows the balloon catheter of Figure 1 in a slightly different configuration;

Figure 6 shows yet another configuration of the balloon catheter;

Figure 7 shows yet a further embodiment of the balloon catheter;

Figure 8 shows yet a further embodiment of the balloon catheter;

Figure 9 shows yet another embodiment of the balloon catheter where the tube is folded back upon itself and wound in a double helix fashion;

Figure 10 shows yet another helical balloon catheter having three helically wound tubes;

Figure 11 shows yet another embodiment of the balloon catheter;

Figure 12 shows another embodiment having a space between successive turns of the balloon to permit circulation through a side branch artery;

Figure 13 shows another embodiment having a space between successive turns of the balloon to give the balloon greater flexibility at a midpoint for use at a sharp bend in an artery;

Figure 14 shows another embodiment having a predetermined curve;

Figure 15 shows a tube that can be wound into the configuration shown in Figure 14, with Figures 15A-15C showing selective cross-sections through lines 15A-15A, 15B-15B, and 15C-15C, respectively;

Figure 16 shows a helical balloon catheter having an outer sheath; and

Figure 17 shows a slightly different embodiment of the helical catheter used as an introducer catheter.

BEST MODE FOR CARRYING OUT THE INVENTION

Figure 1 depicts generally a helical balloon catheter of the invention. The balloon catheter of the invention preferably is comprised of a small thin walled, collapsable tube 32 wound into a helical coil to form a generally cylindrical inflatable balloon portion that has a large open lumen 34 therethrough. The lumen 34 therefore presents a substantially open passageway both distally and proximally, allowing blood to continue flowing through the balloon even when it is inflated.

Successive turns of the helical tube 32 abut one another and are held in position either by adhesive or similar means and/or the intermediate portions 45 of the longitudinal straps 94. In this particular embodiment the straps 94 are attached to a central guide wire 39 at their distal ends 44, and are also attached to the guide wire 39 proximally of the helical portion of the balloon. The proximal portion 36 of the tube 32 itself may also be attached to the guide wire 39, so that the stresses of advancement and withdrawal of the balloon are born by the guide wire 39 and the straps 94, not the tube 32. Such distal and proximal fixation of the straps 94 to the guide wire 39 also longitudinally secures the location of the helical balloon with respect to the guide wire 39. An inflation device 80 is connected to the proximal portion 36 of the tube 32 for inflating and deflating the helical balloon.

Figure 2 depicts the balloon of Figure 1 in its partially inflated configuration, having been advanced into an artery 95 to a narrowed atherosclerotic portion 96 of the artery 95. In Figure 3, the balloon has been inflated to expand the stenotic segment 96 of the artery 95. Because the helical configuration of the balloon catheter provides a large, open lumen 34 when inflated, blood flow through the artery 95 can continue as the angioplasty is being performed, and the balloon can be left inflated for some period of time without restricting blood flow through the artery 95.

If desired, a catheter 41 can be advanced over the guide wire 39 to a position just proximal of the helical portion of the balloon, as shown in Figure 3. This is useful, e.g., for injecting radiographic contrast to aid in imaging or to perfuse the artery with blood or other solutions from an extra-corporeally located device. Blood autoperfusion through the helical balloon catheter may also be enhanced by blood entering side holes in a proximal portion of the catheter 41, e.g., when the balloon catheter is inserted through the aorta to a coronary artery, the blood enters the catheter 41 side holes in the aorta and then travels through the catheter 41 into the coronary artery and through the helical balloon. The catheter 41 may be made of a much larger diameter than the Stack-type catheters because the balloon is not mounted on it, and in some situations the diameter of the catheter 41 may approach the diameter of the inflated helical balloon placed across the stenotic area, providing significant flow therethrough. When a relatively large diameter catheter 41 is used, it may also serve as a guiding catheter to facilitate balloon catheter/guide wire exchanges.

Figure 4 shows that a pushing catheter 42 may also be used to enhance the pushability of the furled helical balloon catheter by transmitting pushing force directly to the furled balloon portion (in addition to the pushing force exerted by the physician on the guide wire 39 itself). The pushing catheter 42 may be advanced over the guide wire 39 to a position abutting the proximal end of the furled balloon portion for assistance in pushing only when actually needed, e.g., for the final push in advancing the balloon portion across the stenotic segment of the artery. Moreover, the pushing catheter may be partially withdrawn or entirely removed once the balloon is in place so as not to impede blood flow through the artery.

Figure 5 shows a slightly modified embodiment of the invention. In this embodiment the straps 94 and tube 32 are not attached to the guide wire 39 proximally of the helical portion so that a more rigid catheter 97 can be advanced over the guide wire 39 beyond the helical portion of the balloon. This is useful, e.g., for increasing the pushability of the guide wire 39. The distal end of this catheter 97 engages the straps 94 near their distal ends 44, pulling the balloon along as the catheter 97 and guide wire 39 are advanced through the artery 95. Figure 6 shows a modification of this embodiment where the guide wire 39 is provided with a flange 98 that is engagable by the distal tip of the catheter 97 to eliminate stress on the straps 94 as the catheter 97 is used to assist in the advancement of the guide wire 39 and balloon.

Figure 7 illustrates an alternate embodiment wherein the straps 94 are attached to a catheter 99 instead of to the guide wire 39. This allows independent advancement and withdrawal of the guide wire 39, but takes up more space in the lumen 34 of the balloon. An additional catheter (not shown) may also be advanced over the catheter 99 until it pushes on the furled balloon, thus further increasing pushability of the system.

Figure 8 shows yet another embodiment wherein the distal ends 44 of the straps 94 return proximally through the central lumen of the catheter 99. In this embodiment, the catheter 99 can be advanced or retracted separately with respect to the balloon, but when the physician grasps the distal and proximal ends 44 and 46 of the straps 94 along with the catheter 99 and simultaneously advances or retracts the catheter 99, the balloon will advance/retract as well (since the intermediate portions 45 of the straps are attached to the coiled tube 32).

Figure 9 shows another configuration for the helical tube 32 in which the helix is formed by a double winding of tube 32, the tube windings being connected to one another at the distal end 37 of the balloon so that, in effect, the balloon consists of a double helical winding of a single tube folded back on itself. In this configuration, the inflation fluid flows into the balloon through one of the windings proximally to distally, and then returns through the other winding distally to proximally. The tube 32 may therefore be entirely flushed of air bubbles, etc., assuring that no air is entrained in the helical tube should the tube burst while in the patient. Figure 9 shows the inflation/flushing device 80 injecting fluid through the tube, with the fluid exiting through the open stop cock 38 at the opposite end of the tube 32.

Figure 10 illustrates that a triple helical winding may also be utilized if desired to form the balloon. The three tubes 32 forming the balloon are attached to the guide wire 39 both distally and proximally of the helical portion of the balloon, their proximal portions 36 being attached to the inflation device 80. Figure 10 also shows an alternate arrangement for the straps 94. In this embodiment, the straps 94 are merely fastened around the helical windings, and do not return proximally.

Figure 11 shows yet another configuration in which the helical windings are attached along one side directly to the guide wire 39, eliminating the need for straps 94 entirely. This configuration has the disadvantage that the balloon is not centered about the guide wire 39 when inflated, even though the need for straps is eliminated.

Referring to Figure 12, if the stenotic segment 96 is located such that the balloon, when inflated, would occlude a side branch 90 of the artery 95, then a modified helical balloon could be utilized that includes a side opening 91, formed by spacing two adjacent turns of the coiled tube 32 slightly from one another. This allows blood to flow out of the lumen 34 into the side branch 90. If desired, radiopaque markers 85 may be placed on the guide wire 39 and/or on the straps 94 to indicate both the longitudinal location of the side opening 91 and the rotational position of the balloon so that the opening 91 in the balloon can be selectively advanced/withdrawn or rotated to the most desirable position.

Figure 13 illustrates another embodiment having a similar opening 91 in the helical balloon. This opening 91 allows the balloon to bend quite dramatically for placement in a bend 89 of the artery 95. The relative lengths of the intermediate portions 45 of the straps 94 can be pre-selected to permit only one side of the balloon to open, thus keeping successive turns of the tube opposite the opening close together, as shown in Figure 12. Again, radiopaque markers 85 may be used to assist in imaging of the longitudinal and rotational position of the balloon.

Figures 14-15 illustrate another technique for manufacturing a balloon with a desired bend. In this embodiment, the tube 32 is manufactured with alternating larger and smaller diameters, as shown in Figure 15. When wound about a mandrel of the proper corresponding diameter, the larger diameter portions 50 of the tube 32 allign on one side, and the smaller diameter portions 51 allign on the other side, giving the coil a natural bend when inflated.

Figure 16 illustrates one possible technique for manufacturing the helical balloon. The tube 32 may be wound into a coiled tube, and then the turns may be secured by either an inner skin or an outer skin 93 as shown in Figure 15. Such a skin may be formed by applying a thin layer of adhesive, by securing a thin layer of silicone, or by other conventional means. The thin inner or outer skin 93 may be applied so thinly that it does not significantly change the shape of the undulating surface, or it may be applied somewhat thicker to smooth out the grooves between successive turns of the tube 32, thereby presenting a smooth surface which can be advantageous in certain circumstances. Other similar techniques may also be utilized to produce the desired configuration.

Figure 17 illustrates an alternate application for use of the helical balloon of the invention in introducing an over-sized device (indicated schematically as 103), for example, through an arthrosclerotic femoral/iliac artery. Here, the helical balloon is advanced while deflated through the femoral/iliac artery 95 to the wider aorta. When the distal end of the balloon has reached the aorta, it may be inflated to present a generally smooth and somewhat straighter pathway for the introduction of devices past arthrosclerotic plaques 96. The use of the inner skin 93 is shown in this embodiment.

While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications may be made therein without departing from the scope of the appended claims.

Claims

1. A helical balloon perfusion angioplasty catheter comprising:

   a tube (32) which defines a tube lumen and which has a proximal, generally straight portion and a distal, helically coiled portion, wherein

   each of the turns of the coiled tube portion defines an internal chamber,
   said internal chambers are interconnected by said tube lumen,
   at least some of the successive turns of the coiled tube portion abut one another,
   the helically coiled portion is inflatable from a deflated, furled configuration having a relatively smaller inner and outer diameter to an inflated, unfurled configuration having a relatively larger inner and outer diameter and forming a balloon having, upon inflation, a both distally and proximally generally open, central catheter lumen (34) defined by the inflated coiled portion, and
   the balloon further includes securing means (93, 94) for securing turns of the coiled portion with respect to one another; and

   advancing means (39, 99, 103) for advancing and retracting the coiled balloon portion in a passageway.

2. The balloon catheter of claim 1 wherein the means for securing comprises a flexible skin (93) attached to at least some of the turns of the coil.

3. The ballon catheter of claim 1 wherein the advancing means comprises a generally central shaft (39, 99) and attachment means (94) for attaching the coiled portion of the balloon to the shaft.

4. The balloon catheter of claim 3 wherein the shaft comprises a guide wire.

5. The balloon catheter of claim 3 wherein the shaft comprises a catheter (99).

6. The balloon catheter of claim 3 wherein the balloon is collapsable and capable of being furled closely about the shaft (39, 99).

7. The balloon catheter of claim 3 further comprising a pushing catheter (42) advancable over the shaft (39), the pushing catheter having a distal end for pushing against the balloon when it is furled about the shaft.

8. The balloon catheter of claim 3 wherein the attachment means comprises straps (94) having distal (44), proximal (46), and intermediate (45) portions.

9. The balloon catheter of claim 8 wherein the distal portions (44) of the straps (94) are attached to the shaft and the intermediate portions (45) of the straps are attached to the coiled portion of the balloon catheter.

10. The balloon catheter of claim 8 wherein the intermediate portions (45) of the straps (94) are attached to the coiled portion of the balloon, and wherein the shaft comprises a catheter (99) having a distal end and a lumen through which the distal portions (44) of the straps (94) may be threaded so that the catheter can be advanced with its distal end engaging the straps near their intermediate portions to advance the balloon catheter.

11. The balloon catheter of claim 8 wherein the distal portions (44) of the straps (94) are attached to the shaft (39), and the intermediate portions (45) of the straps are attached to the coiled portion of the balloon, and further comprising a pushability catheter (97) advancable over the shaft and having a distal end so that the pushability catheter can be advanced over the shaft with its distal end engaging the straps near their distal ends to advance the balloon catheter.

12. The balloon catheter of claim 11 further comprising a stop (98) carried on the shaft (39) so that the distal end of the pushability catheter (97) engages the stop rather than the straps (94).

13. The balloon catheter of claim 1 wherein one of the turns of the coiled portion is spaced from a successive turn to form a gap in the coiled portion, permitting perfusion of a branch artery (90) when the balloon is inflated.

14. The balloon catheter of claim 1 including two such inflatable tubes (32), their coiled portions being coiled in a double helical configuration and being in fluid communication with one another at their distal ends.

15. The balloon catheter of claim 14 wherein the proximal portion of one of the tubes (32) is attachable to an inflation device (80) and the proximal portion of the other tube (32) includes a stopcock (38) that is openable to allow purging of the tube and closable to allow the balloon to be inflated.

16. The balloon catheter of claim 1 wherein the inflatable tube (32) includes first and second ends and is folded upon itself intermediate its ends, the coiled

portion thereby comprising a double helical coil adjacent the fold.

17. The balloon catheter of claim 16 wherein the first end of the tube (32) is attachable to an inflation device (80) and the second end of the tube includes a stopcock (38) that is openable to allow purging of the tube and closable to allow the balloon to be inflated.

18. The balloon catheter of claim 1 further comprising a shaft (39) disposed within the lumen (34), the shaft having a surface that is attached to the turns of the coiled portion.

19. A balloon perfusion angioplasty catheter comprising:

an inflatable tube having a proximal, generally straight portion and a distal, helically coiled, generally cylindrical portion defining a both distally and proximally open, central lumen (34), at least some of the successive turns of the coiled portion abutting one another;
means for securing turns of the coiled portion with respect to one another including a flexible skin (93) attached to at least some of the turns of the coil; and
attachment means for attaching the coiled portion of the balloon to a guide wire (39), comprising straps (94) having distal (44), proximal (46), and intermediate (45) portions, the distal portions of the straps being attached to the guide wire and the intermediate portions of the straps being attached to the coiled portion.

20. A balloon perfusion angioplasty catheter according to claim 1 wherein substantially all of the successive turns of the coiled portion abut one another and define a distal, generally cylindrical inflatable sheath portion, an inflation tube portion extending proximally from the inflatable sheath portion.

21. The balloon catheter of claim 20 wherein means for advancing and retracting the sheath comprises a shaft (39, 99) attached to the inflatable sheath.

22. The balloon catheter of claim 20 wherein the advancing and retracting means comprises a generally central shaft (39, 99) and attachment means (94) for attaching the inflatable sheath portion of the balloon to the shaft.

23. The balloon catheter of claim 22 wherein the shaft comprises a guide wire (39).

24. The balloon catheter of claim 22 wherein the shaft comprises a catheter (99).

25. The balloon catheter of claim 20 wherein the means for advancing and retracting the sheath comprises:

a plurality of straps (94) having proximal (46), intermediate (45), and distal (44) portions, the intermediate portions of the straps being attached to the inflatable sheath, and the distal portions of the straps are attached to the shaft (39, 99).

26. The balloon catheter of claim 25 further comprising a pushing catheter (42) advancable over the shaft (39), the pushing catheter having a distal end for pushing against the balloon when it is furled about the shaft.

27. The balloon catheter of claim 25 wherein the intermediate portions (45) of the straps (94) are attached to the inflatable sheath portion of the balloon, and wherein the shaft comprises a catheter (99) having a distal end and a lumen through which the distal portions (44) of the straps may be threaded so that the catheter can be advanced with its distal end engaging the straps near their intermediate portions to advance the balloon catheter.

28. The balloon catheter of claim 20 wherein the internal diameter of the open lumen through the inflatable sheath portion is at least about one third of the outer diameter of the inflatable sheath portion.

29. The balloon catheter of claim 20 wherein the internal diameter of the open lumen through the inflatable sheath portion is at least about one half of the outer diameter of the inflatable sheath portion.

Patentansprüche

1. Wendelförmiger Perfusions-Angioplastie-Ballonkatheter mit:

einem Tubus (32), der ein Tubuslumen bestimmt und einen proximalen, generell geraden Abschnitt sowie einen distalen, wendelförmig gewundenen Abschnitt aufweist, wobei

jede der Windungen des gewundenen Tubusabschnitts eine Innenkammer bestimmt,
die Innenkammern durch das Tubuslumen miteinander verbunden sind,
mindestens einige der aufeinanderfolgenden Windungen des gewundenen Tubusabschnitts gegeneinander anliegen,
der wendelförmig gewundene Abschnitt aus einer entleerten, zusammengelegten Konfiguration mit einem relativ kleineren Innen- und Außendurchmeser zu einer

aufgeblähten, entfalteten Konfiguration mit einem relativ größeren Innen- und Außendurchmesser aufgebläht werden kann, wobei ein Ballon gebildet wird, der bei und nach dem Aufblähen ein sowohl distal als auch proximal generell offenes, zentrales Katheterlumen (34) aufweist, das durch den aufgeblähten, gewundenen Abschnitt gebildet wird, und

wobei der Ballon ferner eine Sicherungsanordnung (93, 94) aufweist, um Windungen des gewundenen Abschnitts gegeneinander zu sichern; und

einer Vorschubanordnung (39, 99, 103) zum Vorschieben und Zurückziehen des gewundenen Ballonabschnitts in einem Durchgang.

2. Ballonkatheter nach Anspruch 1, bei welchem die Sicherungsanordnung eine flexible Haut (93) aufweist, die an mindestens einigen der Windungen des gewundenen Abschnitts befestigt ist.

3. Ballonkatheter nach Anspruch 1, bei welchem die Vorschubanordnung einen generell zentralen Schaft (39, 99) und eine Befestigungsanordnung (94) zum Befestigen des gewundenen Abschnitts des Ballons an dem Schaft aufweist.

4. Ballonkatheter nach Anspruch 3, bei welchem der Schaft einen Führungsdraht aufweist.

5. Ballonkatheter nach Anspruch 3, bei welchem der Schaft ein Katheter (99) ist.

6. Ballonkatheter nach Anspruch 3, bei welchem der Ballon kollabierbar ist und sich eng um den Schaft (39, 99) zusammenlegen läßt.

7. Ballonkatheter nach Anspruch 3, ferner versehen mit einem über den Schaft (39) vorschiebbaren Schiebekatheter (42) mit einem distalen Ende, welches gegen den Ballon drückt, wenn dieser um den Schaft zusammenlegt ist.

8. Ballonkatheter nach Anspruch 3, bei welchem die Befestigungsanordnung Strapse (94) mit distalen (44), proximalen (46) und dazwischen liegenden (45) Bereichen aufweist.

9. Ballonkatheter nach Anspruch 8, bei welchem die distalen Bereiche (44) der Strapse (94) an dem Schaft befestigt sind und die dazwischen liegenden Bereiche (45) der Strapse an dem gewundenen Abschnitt des Ballonkatheters angebracht sind.

10. Ballonkatheter nach Anspruch 8, bei welchem die dazwischen liegenden Bereiche (45) der Strapse (94) an dem gewundenen Abschnitt des Ballonkatheters angebracht sind, und wobei der Schaft ein Katheter (99) mit einem distalen Ende und einem Lumen ist, durch welches die distalen Bereiche (44) der Strapse (94) gefädelt werden können, so daß beim Vorbewegen des Katheters dessen distales Ende mit den Strapsen nahe deren dazwischen liegenden Bereichen in Eingriff steht, um den Ballokatheter vorzubewegen.

11. Ballonkatheter nach Anspruch 8, bei welchem die distalen Bereiche (44) der Strapse (94) an dem Schaft (39) befestigt sind und die dazwischen liegenden Bereiche (45) der Strapse an dem gewundenen Abschnitt des Ballonkatheters angebracht sind, und wobei ferner ein vorschiebbarer Katheter (97) vorgesehen ist, der über den Schaft vorbewegt werden kann und ein distales Ende aufweist, so daß beim Vorbewegen des vorschiebbaren Katheters über den Schaft das distale Katheterende mit den Strapsen nahe deren distalen Enden in Eingriff steht, um den Ballokatheter vorzubewegen..

12. Ballonkatheter nach Anspruch 11, ferner versehen mit einem auf dem Schaft (39) getragenen Anschlag (98), so daß das distale Ende des vorschiebbaren Katheters (97) mit dem Anschlag anstatt mit den Strapsen (94) in Eingriff tritt.

13. Ballonkatheter nach Anspruch 1, bei welchem eine der Windungen des gewundenen Abschnitts in Abstand von einer nachfolgenden Windung angeordnet ist, um einen Spalt in dem gewundenen Abschnitt zu bilden, der eine Perfusion einer Zweigarterie (90) gestattet, wenn der Ballon aufgebläht ist.

14. Ballonkatheter nach Anspruch 1, versehen mit zwei aufweitbaren Tuben (32) deren gewundene Abschnitte nach Art einer Doppelhelix gewunden sind und die an ihren distalen Enden in Fluidverbindung miteinander stehen.

15. Ballonkatheter nach Anspruch 14, bei welchem der proximale Abschnitt von einem der Tuben (32) an einer Inflationsvorrichtung (80) befestigbar ist und der proximale Abschnitt der anderen Tubus (32) einen Absperrhahn (38) aufweist, der geöffnet werden kann, um ein Spülen des Tubus zu gestatten, und der geschlossen werden kann, um ein Aufblähen des Ballons zu ermöglichen.

16. Ballonkatheter nach Anspruch 1, bei welchem der aufblähbare Tubus (32) ein erstes und ein zweites Ende aufweist und zwischen dessen Enden auf sich selbst gefaltet ist, wobei der gewundene Abschnitt benachbart dem Falz eine Doppelhelix aufweist.

17. Ballonkatheter nach Anspruch 16, bei welchem das erste Ende des Tubus (32) an einer Inflationsvorrichtung (80) befestigbar ist und das zweite Ende des Tubus einen Absperrhahn (38) aufweist, der geöffnet werden kann, um ein Spülen des Tubus zu gestatten, und der geschlossen werden kann, um ein Aufblähen des Ballons zu ermöglichen.

18. Ballonkatheter nach Anspruch 1, ferner versehen mit einem innerhalb des Lumens (34) angeordneten Schaft (39), der eine Oberfläche aufweist, die an den Windungen des gewundenen Abschnitts angebracht ist.

19. Perfusions-Ballonkatheter zur Angioplastie versehen mit:

einem aufblähbaren Tubus mit einem proximalen, generell geraden Abschnitt sowie einem distalen, wendelförmig gewundenen, generell zylindrischen Abschnitt, der ein sowohl distal als auch proximal offenes zentrales Lumen (34) aufweist, wobei mindestens einige der aufeinanderfolgenden Windungen des gewundenen Abschnitts gegeneinander anliegen;
einer Anordnung zum Sichern von Windungen des gewundenen Abschnitts gegeneinander, die eine flexible Haut (93) aufweist, die an mindestens einigen der Windungen des gewundenen Abschnitts befestigt ist; und
einer Befestigungsanordnung zum Befestigen des gewundenen Abschnitts des Ballons an einem Führungsdraht (39), die Strapse (94) mit distalen (44), proximalen (46) und dazwischen liegenden (45) Bereichen aufweist, wobei die distalen Bereiche der Strapse an dem Führungsdraht befestigt sind und die dazwischen liegenden Bereiche der Strapse an dem gewundenen Abschnitt angebracht sind.

20. Perfusions-Angioplastie-Ballonkatheter nach Anspruch 1, bei welchem im wesentlichen alle der aufeinanderfolgenden Windungen des gewundenen Abschnitts gegeneinander anliegen und einen distalen, im wesentlichen zylindrischen, aufblähbaren Umhüllungsbereich bestimmen, wobei ein Inflationstubusabschnitt proximal von dem aufblähbaren Umhüllungsbereich verläuft.

21. Ballonkatheter nach Anspruch 20, bei welchem die Anordnung zum Vorbewegen und zum Zurückziehen der Umhüllung einen Schaft (39, 99) aufweist, der an der aufblähbaren Umhüllung befestigt ist.

22. Ballonkatheter nach Anspruch 20, bei welchem die Anordnung zum Vorbewegen und zum Zurückziehen einen generell zentralen Schaft (39, 99) und eine Befestigungsanordnung (94) zum Befestigen des aufblähbaren Umhüllungsbereichs des Ballons an dem Schaft aufweist.

23. Ballonkatheter nach Anspruch 22, bei welchem der Schaft einen Führungsdraht (39) aufweist.

24. Ballonkatheter nach Anspruch 22, bei welchem der Schaft ein Katheter ist.

25. Ballonkatheter nach Anspruch 20, bei welchem die Anordnung zum Vorbewegen und zum Zurückziehen der Umhüllung versehen ist mit:

einer Mehrzahl von Strapsen (94) mit distalen (44), proximalen (46) und dazwischen liegenden (45) Bereichen, wobei die dazwischen liegenden Bereiche der Strapse an der aufblähbaren Umhüllung befestigt sind und die distalen Bereiche an dem Schaft angebracht sind.

26. Ballonkatheter nach Anspruch 25, ferner versehen mit einem Vorschiebekatheter (42) der über den Schaft (39) vorbewegt werden kann und ein distales Ende aufweist, welches gegen den Ballon drückt, wenn er um den Schaft zusammengelegt ist.

27. Ballonkatheter nach Anspruch 25, bei welchem die dazwischen liegenden Bereiche (45) der Strapse (94) an dem aufblähbaren Umhüllungsbereich des Ballons angebracht sind, und wobei der Schaft einen Katheter (99) mit einem distalen Ende und einem Lumen aufweist, durch welches die distalen Bereiche (44) der Strapse gefädelt werden können, so daß beim Vorbewegen des Katheters dessen distales Ende mit den Strapsen nahe deren dazwischen liegenden Bereichen in Eingriff steht, um den Ballokatheter vorzubewegen.

28. Ballonkatheter nach Anspruch 20, bei welchen der Innendurchmesser des offenen Lumens durch den aufblähbaren Umhüllungsbereich mindestens ein Drittel des Außendurchmessers des aufblähbaren Umhüllungsbereichs ausmacht.

29. Ballonkatheter nach Anspruch 20, bei welchen der Innendurchmesser des offenen Lumens durch den aufblähbaren Umhüllungsbereich mindestens die Hälfte des Außendurchmessers des aufblähbaren Umhüllungsbereichs ausmacht.

Revendications

1. Cathéter à ballonnet hélicoïdal d'angioplastie par perfusion, comprenant :

un tube (32) qui comporte un passage de tube

et qui a une partie proximale sensiblement rectiligne et une partie distale enroulée en hélice, dans lequel

chacune des spires de la partie enroulée de tube constitue une chambre interne, lesdites chambres internes sont raccordées par ledit passage de tube,
au moins certaines des spires successives de la partie enroulée de tube sont en butées les unes contre les autres,
la partie enroulée en hélice est gonflable d'une forme dégonflée resserrée ayant des diamètres intérieur et extérieur relativement petits à une forme gonflée desserrée ayant des diamètres intérieur et extérieur relativement grands et formant un ballonnet ayant après gonflage un passage central de cathéter (34) sensiblement ouvert à toutes les deux extrémités distale et proximale et délimité par la partie enroulée gonflée et
le ballonnet comprend par ailleurs un moyen de fixation (93, 94) pour fixer les spires de la partie enroulée les unes par rapport aux autres ; et

un moyen d'avance (39, 99, 103) pour faire avancer et mettre en retrait la partie enroulée du ballonnet à l'intérieur d'un passage.

2. Cathéter à ballonnet selon la revendication 1, dans lequel le moyen de fixation consiste en une gaine souple (93) fixée à au moins certaines des spires de l'enroulement.

3. Cathéter à ballonnet selon la revendication 1, dans lequel le moyen d'avance comprend une tige sensiblement centrale (39, 99) et un moyen de fixation (94) pour fixer la partie enroulée du ballonnet à la tige.

4. Cathéter à ballonnet selon la revendication 3, dans lequel la tige consiste en un fil métallique de guidage.

5. Cathéter à ballonnet selon la revendication 3, dans lequel la tige consiste en un cathéter (99).

6. Cathéter à ballonnet selon la revendication 3, dans lequel le ballonnet est rétractable et capable d'être serré étroitement autour de la tige (39, 99).

7. Cathéter à ballonnet selon la revendication 3, comprenant par ailleurs un cathéter poussant (42) pouvant être avancé sur la tige (39), le cathéter poussant ayant une extrémité distale destinée à exercer une poussée contre le ballonnet lorsqu'il est serré autour de la tige.

8. Cathéter à ballonnet selon la revendication 3, dans lequel le moyen de fixation consiste en des sangles (94) ayant des parties distales (44), proximales (46) et intermédiaires (45).

9. Cathéter à ballonnet selon la revendication 8, dans lequel les parties distales (44) des sangles (94) sont fixées à la tige et les parties intermédiaires (45) des sangles sont fixées à la partie enroulée du cathéter à ballonnet.

10. Cathéter à ballonnet selon la revendication 8, dans lequel les parties intermédiaires (45) des sangles (94) sont fixées à la partie enroulée du ballonnet et dans lequel la tige consiste en un cathéter (99) ayant une extrémité distale ainsi qu'un passage par lequel les parties distales (44) des sangles (94) peuvent être enfilées de manière que le cathéter puisse être avancé en ayant son extrémité distale en appui contre les sangles à proximité de leurs parties intermédiaires pour faire avancer le cathéter à ballonnet.

11. Cathéter à ballonnet selon la revendication 8, dans lequel les parties distales (44) des sangles (94) sont fixées à la tige (39) et les parties intermédiaires (45) des sangles sont fixées à la partie enroulée du ballonnet, et comprenant par ailleurs un cathéter (97) d'exercice d'une poussée, pouvant être avancé sur la tige et ayant une extrémité distale, de manière que le cathéter d'exercice d'une poussée puisse être avancé sur la tige en ayant son extrémité distale en appui contre les sangles à proximité de leurs extrémités distales pour faire avancer le cathéter à ballonnet.

12. Cathéter à ballonnet selon la revendication 11, comprenant par ailleurs une butée (98) portée par la tige (39) de manière que l'extrémité distale du cathéter d'exercice d'une poussée (97) prenne appui contre la butée et non pas contre les sangles (94).

13. Cathéter à ballonnet selon la revendication 1, dans lequel une des spires de la partie enroulée est distante d'une spire successive de manière à former un intervalle dans la partie enroulée afin de permettre la perfusion d'une artère d'embranchement (90) lorsque le ballonnet est gonflé.

14. Cathéter à ballonnet selon la revendication 1, comprenant deux de ces tubes gonflables (32), leur partie enroulée étant enroulée à une forme hélicoïdale double et étant en communication fluidique l'un avec l'autre à leurs extrémités distales.

15. Cathéter à ballonnet selon la revendication 14, dans lequel la partie proximale de l'un des tubes (32) peut se fixer à un dispositif de gonflage (80) et la partie proximale de l'autre tube (32) comprend un robinet d'arrêt (38) qui peut être ouvert afin de purger le tube et qui peut être fermé pour permettre au ballonnet d'être gonflé.

16. Cathéter à ballonnet selon la revendication 1, dans lequel le tube gonflable (32) comprend des première et seconde extrémités et est replié sur lui-même entre ses extrémités, la partie enroulée comprenant ainsi un enroulement hélicoïdal double qui est contigu au pli.

17. Cathéter à ballonnet selon la revendication 16, dans lequel la première extrémité du tube (32) peut se fixer à un dispositif de gonflage (80) et la seconde extrémité du tube comprend un robinet d'arrêt (38) qui peut être ouvert pour permettre la purge du tube et qui peut être fermé pour permettre au ballonnet d'être gonflé.

18. Cathéter à ballonnet selon la revendication 1, comprenant par ailleurs une tige (39) disposée à l'intérieur du passage (34), la tige ayant une surface qui est fixée aux spires de la partie enroulée.

19. Cathéter à ballonnet d'angioplastie par perfusion, comprenant :

un tube gonflable ayant une partie proximale sensiblement rectiligne et une partie distale enroulée en hélice, sensiblement cylindrique, délimitant un passage central (34) ouvert à toutes les deux extrémités distale et proximale, au moins certaines des spires successives de la partie enroulée étant en butée les unes contre les autres ;

un moyen de fixation des spires de la partie enroulée les unes par rapport aux autres, comprenant une gaine souple (93) fixée à au moins certaines des spires de l'enroulement ; et

un moyen de fixation destiné à fixer la partie enroulée du ballonnet à un fil métallique de guidage (39) et comprenant des sangles (94) ayant des parties distales (44), proximales (46) et intermédiaires (45), les parties distales des sangles étant fixées au fil métallique de guidage et les parties intermédiaires des sangles étant fixées à la partie enroulée.

20. Cathéter à ballonnet d'angioplastie par perfusion selon la revendication 1, dans lequel sensiblement toutes les spires successives de la partie enroulée sont en butée les unes contre les autres et constituent une partie distale de gaine gonflable sensiblement cylindrique, une partie de tube de gonflage partant de l'extrémité proximale de la partie de gaine gonflable.

21. Cathéter à ballonnet selon la revendication 20, dans lequel un moyen pour faire avancer et mettre en retrait la gaine consiste en une tige (39, 99) fixée à la gaine gonflable.

22. Cathéter à ballonnet selon la revendication 20, dans lequel le moyen pour faire avancer et mettre en retrait consiste en une tige sensiblement centrale (39, 99) et en un moyen de fixation (94) pour fixer la partie de gaine gonflable du ballonnet à la tige.

23. Cathéter à ballonnet selon la revendication 22, dans lequel la tige consiste en un fil métallique de guidage (39).

24. Cathéter à ballonnet selon la revendication 22, dans lequel la tige consiste en un cathéter (99).

25. Cathéter à ballonnet selon la revendication 20, dans lequel le moyen pour faire avancer et mettre en retrait la gaine comprend :

plusieurs sangles (94) ayant des parties proximales (46), intermédiaires (45) et distales (44), les parties intermédiaires des sangles étant fixées à la gaine gonflable et les parties distales des sangles étant fixées à la tige (39, 99).

26. Cathéter à ballonnet selon la revendication 25, comprenant par ailleurs un cathéter poussant (42) qu'il est possible de faire avancer sur la tige (39), le cathéter poussant ayant une extrémité distale d'exercice d'une poussée contre le ballonnet lorsque celui-ci est serre autour de la tige.

27. Cathéter à ballonnet selon la revendication 25, dans lequel les parties intermédiaires (45) des sangles (94) sont fixées à la partie de gaine gonflable du ballonnet et dans lequel la tige consiste en un cathéter (99) ayant une extrémité distale et un passage par lequel les parties distales (44) des sangles peuvent être enfilées de manière que le cathéter puisse être avancé en ayant son extrémité distale en appui contre les sangles à proximité de leurs parties intermédiaires pour faire avancer le cathéter à ballonnet.

28. Cathéter à ballonnet selon la revendication 20, dans lequel le diamètre interne du passage ouvert situé dans la partie de gaine gonflable est au moins d'environ un tiers du diamètre extérieur de la partie de gaine gonflable.

29. Cathéter à ballonnet selon la revendication 20,

dans lequel le diamètre interne du passage ouvert situé dans la partie de gaine gonflable est d'au moins une moitié du diamètre extérieur de la partie de gaine gonflable.

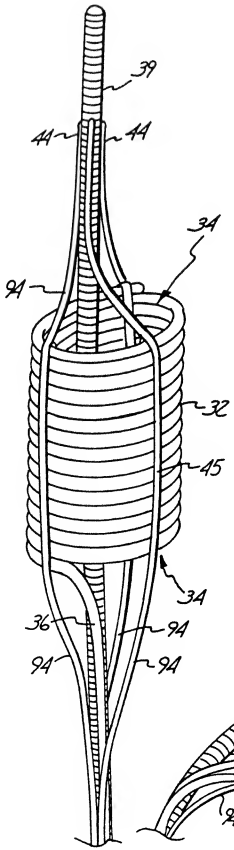
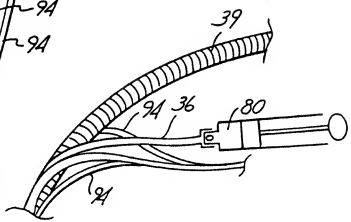


Fig. 1



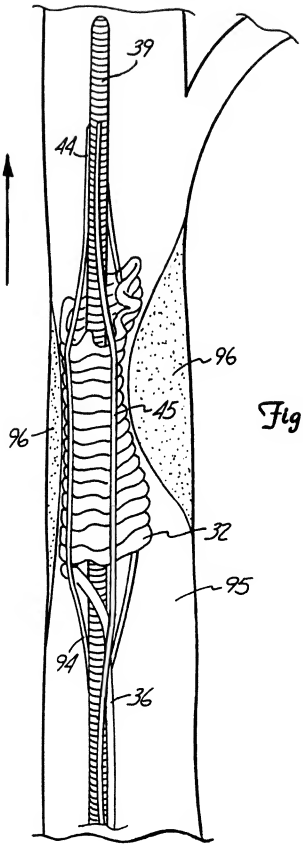
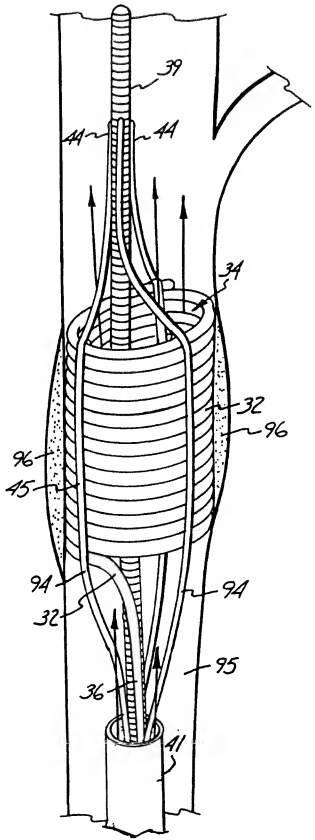


Fig. 2

Fig.3



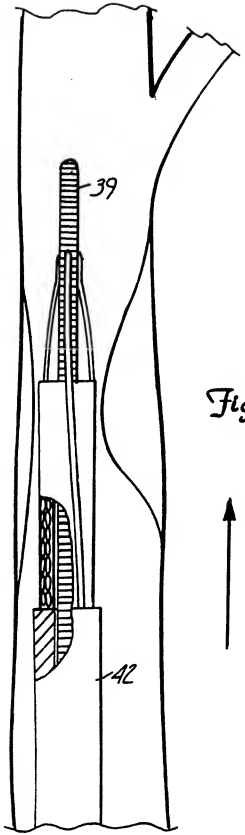


Fig. 4

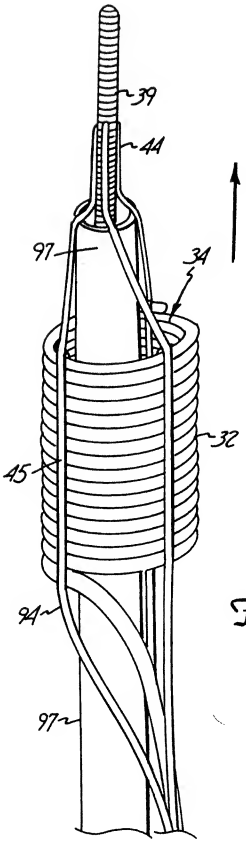


Fig.5

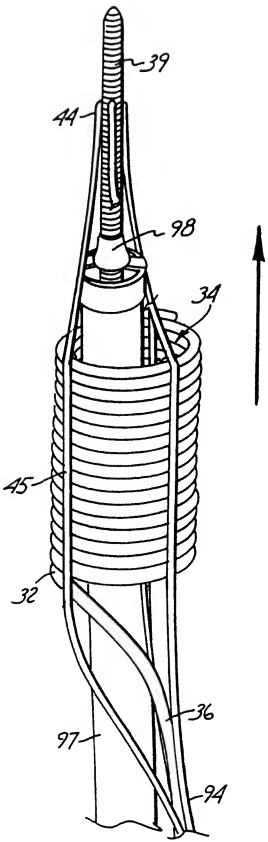


Fig. 6

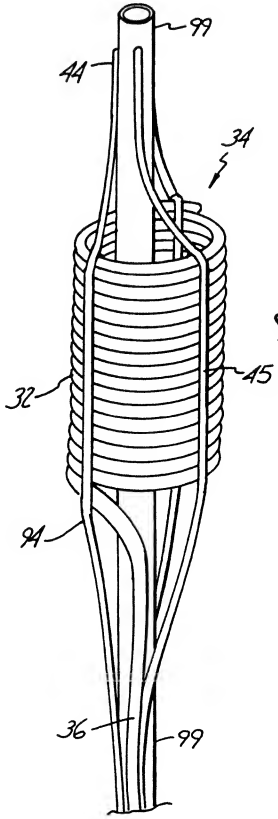


Fig. 7

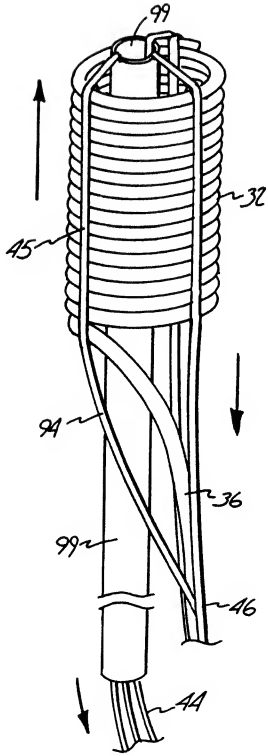


Fig. 8

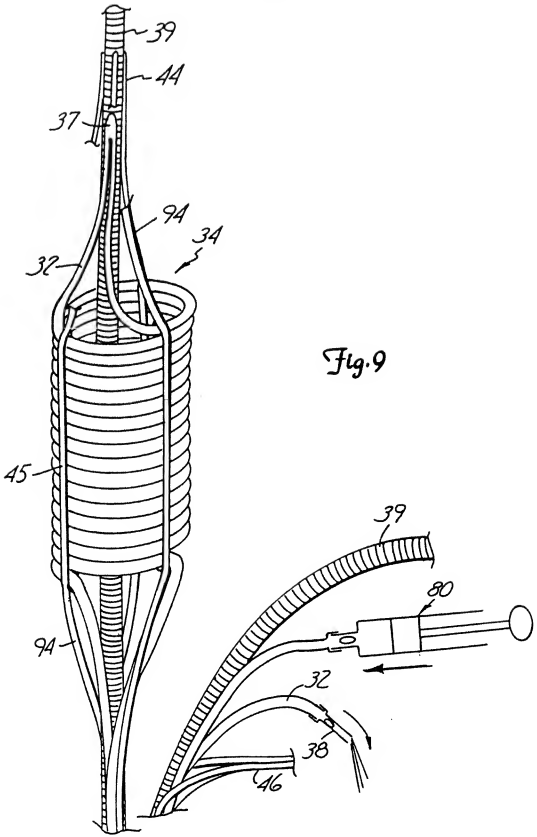


Fig.9

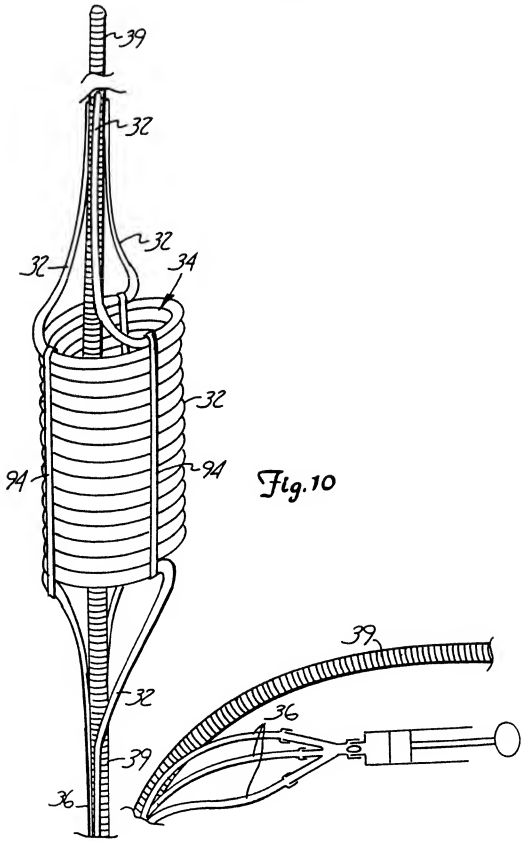


Fig.10

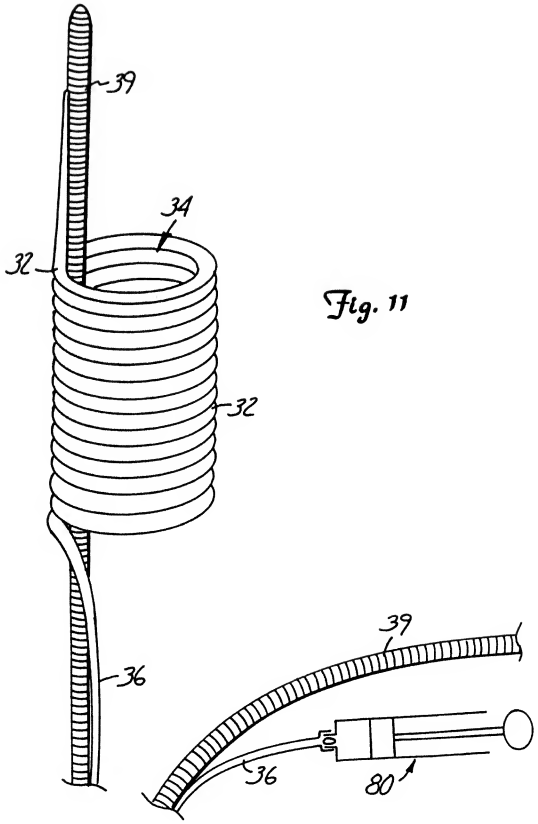


Fig. 11

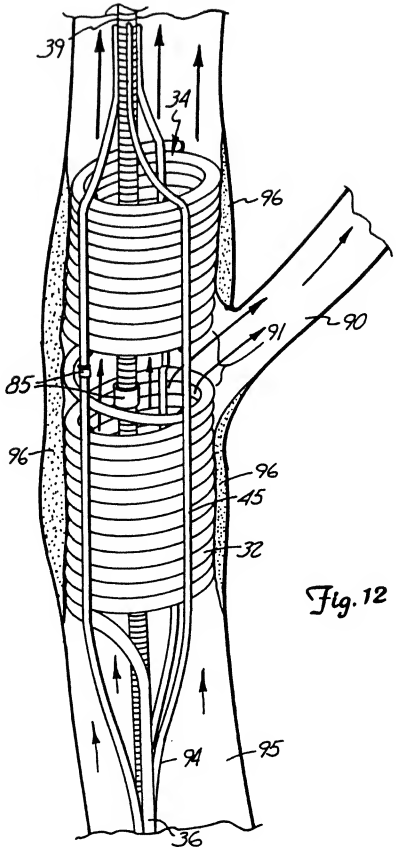


Fig. 12

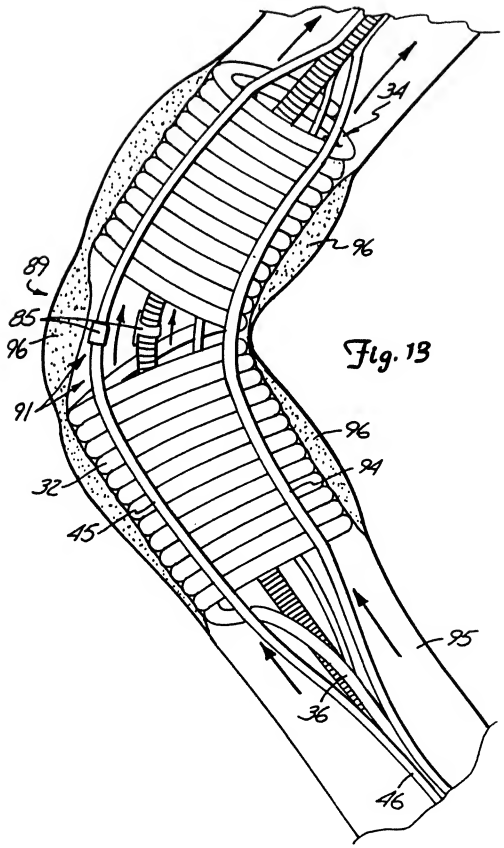


Fig. 13

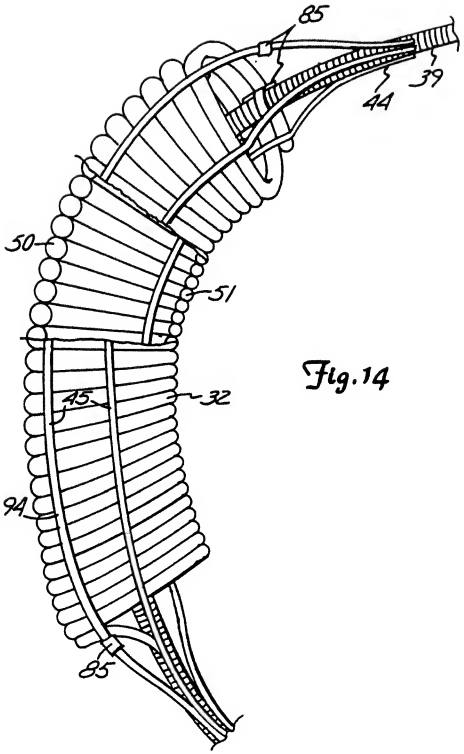


Fig.14

Fig. 15

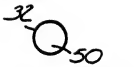


Fig. 15A

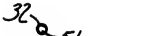


Fig. 15B

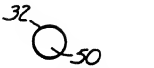


Fig. 15C

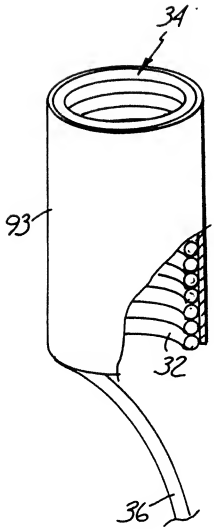


Fig. 16

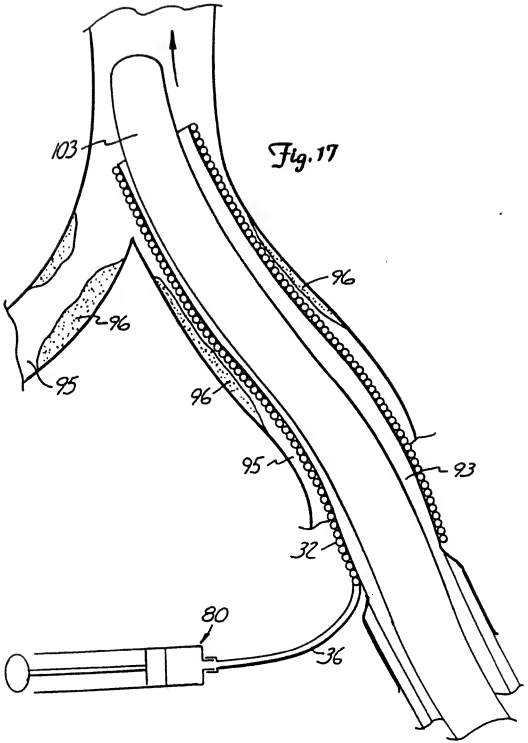


Fig. 17